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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,725	09/08/2003	Louis C. Smith	AVSI-0010 P1	8903

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VGX Pharmaceuticals, LLC
1787 Sentry Parkway West
Building 18, Suite 400
Blue Bell, PA 19422

EXAMINER	
BOUCHELLE, LAURA A	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
08/16/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US.Patents@inovio.com

Office Action Summary	Application No.	Applicant(s)	
	10/657,725	SMITH ET AL.	
	Examiner	Art Unit	
	LAURA BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15,18,19 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15,18,19 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/11 has been entered.

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/360,768, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. A waveform generator and waveform logger are not disclosed. The controller being capable of sampling and monitoring the electroporation voltage

and current waveforms, and the waveform logger being capable of recording the electroporation voltage and waveforms are not disclosed.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 4-15, 18, 19, 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draghia-Akli et al (US 7,245,963) in view of Simon (US 2002/0010415).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

4. Draghia-Akli discloses an electroporation device comprising a support structure that includes a sterile injection channel, an electrode assembly having a plurality of needle electrodes mounted in an array around the sterile injection channel, a current generator in communication with the plurality of needle electrodes, the generator capable of generating an electrical pulse, a power source, a controller, the controller capable of managing the electroporation device to expose tissue adjacent to the needle electrodes to substantially constant current independent of any resistance change in the tissue during the electrical pulse (col. 12, lines 19-40, col. 17, lines 56-60, see fig. 4). The device includes an input device 34, 36, 38 in the form of a keypad (col. 11, lines 19-20, see fig. 5). A status reporting device (LEDs 62, 64, 54) report status information during use (col. 11, lines 26-28). The system may be provided with a battery (col. 5, lines 36-37). The electrode assembly comprises a handle 1 (portion in black in fig 4), the sterile channel extends through a portion of the handle. The array is circular (col. 9, lines 44-46).

5. Draghia-Akli discloses a method of electroporating cells comprising the steps of programming a pulse pattern into a controller of the electroporation device described above, the controller manages the device to expose tissue to a constant current independent of any resistance change in the tissue during the electrical pulse (col. 17, lines 56-60), the electrodes are inserted into the tissue,

6. Draghia-Akli fails to disclose that the controller is capable of sampling and monitoring the voltage and waveforms, and a waveform logger capable of recording the voltage and waveforms. Simon teaches an electroporation device that includes a waveform logger that measures and records the voltage and current delivered through the electrodes so that the patient's response to the treatment can be compared to a baseline and monitored over time and

the performance of the system and the pharmaceutical can be assessed (page 6, paragraph 0060). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Draghia-Akli to include a waveform logger as taught by Simon so that the performance of the treatment can be assessed.

7. Claims 9, 10 differ from the teachings above in calling for an optical serial port or an infrared port. However, wireless communication is well known in the medical device art in general and is provided in order to make use of the device easier for the patient and medical technician. At the time of invention, it would have been obvious to incorporate an optical serial port or an IR port into the invention to Draghia-Akli. These devices are well known in the art and the motivation for the incorporation would have been known generally by one skilled in the art to make use of the device easier for the patient and the medical technician and thereby enhancing the device in general.

8. Claims 11, 12 differ from Draghia-Akli in calling for memory in communication with the controller. Simon teaches that the controller includes memory that allows the signals to be generated and controlled (page 14, paragraph 0139). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Draghia-Akli to include a memory as taught by Simon so that the controller can generate the signal.

9. Claim 19 differs from Draghia-Akli in calling for the diameter of the circular array to be about 1.0 cm. This would have been a matter of obvious design choice. It is well known in the medical arts to adjust the size and arrangement of needles and electrodes to meet the needs of the procedure being performed. The size of a treatment area can vary widely from patient to patient

based on the size of the person. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle array to have a diameter of about 1 cm.

10. Claims 3, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draghia-Akli et al in view of Simon as applied to claim 1 above, and further in view of Jacobsen et al (US 4,141,359).

11.

12. Claim 3 differs from the teachings above in calling for an impedance tester in electrical communication with the plurality of needles. Jacobsen teaches an electroporation device having an impedance tester to monitor the resistance of the tissue to ensure that the current remains constant (col. 6, lines 22-26). It would have been obvious to modify the device of Draghia-Akli to include an impedance tester as taught by Jacobsen so that the user can ensure that the needles remain in contact with the tissue to prevent voltage spikes that could cause injury.

13. Regarding claim 27, Draghia-Akli discloses a method of electroporating cells comprising the steps of programming a pulse pattern into a controller of the electroporation device described above, the controller manages the device to expose tissue to a constant current independent of any resistance change in the tissue during the electrical pulse (col. 17, lines 56-60), the electrodes are inserted into the tissue, a solution of macromolecules is injected the tissue and a pulse of energy is applied (abstract).

14. Draghia-Akli fails to disclose that the controller is capable of sampling and monitoring the voltage and waveforms, and a waveform logger capable of recording the voltage and waveforms. Simon teaches an electroporation device that includes a waveform logger that

measures and records the voltage and current delivered through the electrodes so that the patient's response to the treatment can be compared to a baseline and monitored over time and the performance of the system and the pharmaceutical can be assessed (page 6, paragraph 0060). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Draghia-Akli to include a waveform logger as taught by Simon so that the performance of the treatment can be assessed.

15. Claim 27 also differs from the teachings above in calling for an impedance tester in electrical communication with the plurality of needles. Jacobsen teaches an electroporation device having an impedance tester to monitor the resistance of the tissue to ensure that the current remains constant (col. 6, lines 22-26). It would have been obvious to modify the device of Draghia-Akli to include an impedance tester as taught by Jacobsen so that the user can ensure that the needles remain in contact with the tissue to prevent voltage spikes that could cause injury.

Response to Arguments

16. Applicant's arguments filed 7/21/11. In light of the amendments, a new ground(s) of rejection is made in view of Draghia-Akli et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Primary Examiner
Art Unit 3763

/Laura A Bouchelle/
Primary Examiner, Art Unit 3763